

## **Board of Pharmacy**

### **Initial Statement of Reasons**

Subject Matter of Proposed Regulation:      Quality Assurance Programs

Sections Affected: 1711

#### Problem Addressed

Recent studies have highlighted the high number of medication errors and their adverse health consequences. The most notable of these studies is “To Err Is Human” published by the Institute of Medicine (IOM). This study comprehensively examines the literature on patient safety and makes numerous policy recommendations. Among those recommendations is the suggestion that all health care organizations implement quality improvement programs to reduce medical errors.

#### Specific Purpose of the Regulation

This proposed regulation fulfills the board’s obligation to adopt regulations specifying the requirements for quality assurance programs in pharmacies that was established in Senate Bill 1339 (Chapter 677, Statutes of 2000). These regulations are designed to establish quality assurance programs that will effect a reduction in the incidence of medication errors in pharmacies.

Section 1711 would be added.

Subdivision (a) requires pharmacies to establish quality assurance programs consistent with this section.

Subdivision (b) defines medication error.

Subdivision (c) requires pharmacies to have written policies and procedures describing the quality assurance program. This subdivision also requires that information regarding the error and corrective actions are communicated to the subject of the error and the healthcare team.

Subdivision (d) requires quality assurance programs to have a process to detect medication errors. It further requires that an investigation of the error commence as soon as possible. Lastly, if the investigation indicates that the error is attributable in whole or in part to the pharmacy or its personnel a quality assurance review must be performed.

Subdivision (e) specifies the minimum elements required in a quality assurance review to include an investigation, documentation of the error, and an “essential cause examination.”

Subdivision (f) defines “essential cause examination.”

Subdivision (g) requires that records relating to the quality assurance review must be retained in the pharmacy.

Subdivision (h) prohibits the discovery of the proceedings or records in a quality assurance review.

Subdivision (i) permits the board to consider compliance with the quality assurance program as a mitigating factor in an investigation.

Subdivision (j) permits pharmacies to contract with third parties to perform quality assurance reviews.

Subdivision (k) specifies that this section becomes operative on January 1, 2002.

### Factual Basis

The following are among the statistics cited by the Institute of Medicine to establish the unacceptably high number of deaths and injuries that result from medical errors.

- Medication errors are estimated to kill more than 7,000 patients per year nationwide.
- Between 1983 and 1993 there was an 8 fold increase in deaths attributable to medication errors, compared to a 2 fold increase in hospital deaths in the United States.
- The cost of hospital-related medication errors alone exceeds \$2 billion per year. Hospital patients account for a fraction of all prescriptions filled each year.
- One study found that 4.2 percent of outpatient prescriptions result in adverse drug reactions. Pharmacies dispense over 2.5 billion prescriptions each year.

These statistics (assuming 10% of all prescriptions are written in California) indicate that over 1 million adverse drug reactions occur each year in California on an outpatient basis alone. A great many of these reactions are preventable medication errors and inflict pain, loss of function and economic loss on consumers. The board believes there is no acceptable incidence of medication errors in a pharmacy. Any error needs to be thoroughly evaluated to prevent its recurrence. The purpose of this proposed regulation is to establish the processes needed to evaluate medication errors and make corresponding improvements in pharmacy operations.

### Underlying Data

In developing these regulations, the board relied heavily on other quality assurance models in healthcare institutions and the substantial literature available on quality improvement. The Sentinel Event policy adopted by the Joint Commission on Accreditation of Health Care Organizations provided some of the framework of the proposed regulation. Among the most significant elements drawn from the Sentinel Event program is root cause analysis. Root cause analysis is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence of a given medication error. Essentially root cause analysis is a method of structured inquiry that will yield the most fundamental source of error. The board has established a similar technique which is implemented as “essential cause analysis” in the proposed regulation. The change in nomenclature is to distinguish the use of “essential cause analysis” in the pharmacy setting from the use of “root cause analysis” to satisfy accreditation requirements for hospitals and other licensed care facilities.

### Business Impact

This regulation will require pharmacies to implement quality assurance programs to reduce medication errors. This will require resources both to develop these programs and to perform those tasks required by the regulation. The regulation explicitly permits pharmacies to contract for these services and it is anticipated that private sector organizations will develop programs for sale to pharmacies.

#### Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

#### Consideration of Alternatives

The board has not identified any equally effective alternatives that would lessen any adverse impact on business.